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14. ABSTRACT
Problem statement. In rehabilitation for military personnel and veterans with TBI, we currently face two fundamental problems. First, for those with motor and cognitive dysfunction, current treatment does not restore many to normal everyday function and life role participation. Purpose. Therefore, the purpose of this study is to restore function and life role participation for military personnel and veterans with TBI by customizing, applying, and testing an integrated cognitive and motor training protocol that was successful in other populations with problems similar to TBI. Design summary. This will be an A-B study design, with subjects serving as control subjects during Phase A (standard care) and as experimental subjects during Phase , during which they will receive 12 weeks of cognitive and motor training, 5 times per week, 5 hours/session.

15. SUBJECT TERMS- none provided

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Restoration of Life Role Participation through Integrated Cognitive and Motor Training for Individuals with TBI

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Section I Introduction

Problem statement. In rehabilitation for military personnel and veterans with TBI, we currently face two fundamental problems. First, for those with motor and cognitive dysfunction, current treatment does not restore many to normal everyday function and life role participation. Life role participation is the performance of activities as an employee, parent, friend, spouse, family member, or volunteer. The second problem is that some research studies show promising results, but only within the narrow focus of each study and have fallen short, not restoring function and life role participation.

There are three potential reasons that interventions, to date, have shown incomplete results: 1) absence of a strong basis in relevant principles of brain plasticity and re-learning; 2) insufficient array of targeted interventions; 3) incomplete attention to training specificity and the necessity of training in the everyday environment specifically on the activities of life role participation.

In background work with patients with TBI or who had impairments similar to TBI, we used the principles of brain plasticity for motor and cognitive training. We targeted the necessary array of impairments and incorporated training specificity into the protocol, including life role activities. In our work, we demonstrated significant gains in cognitive function and significant gains in motor control that were sufficiently robust to produce significant gains in function and life role participation, for those with impairments similar to TBI. In our background work, we used a judicious selection of technologies that ensured adherence to the necessary brain plasticity/motor learning principles, as well as ensuring that we addressed the required array of impairment obstacles preventing restoration of function and life role participation.

Purpose. Therefore, the purpose of this study is to restore function and life role participation for military personnel and veterans with TBI by customizing, applying, and testing an integrated cognitive and motor training protocol that was successful in other populations with problems similar to TBI.

Methods. Design summary. This will be an A-B study design, with subjects serving as control subjects during Phase A and as experimental subjects during Phase B. Phase A will consist of standard, usual care, as originally planned for the control group. Phase B will consist of the planned intervention, described below in the original plan. Subjects with TBI > 6 months will be enrolled in order to determine pre-/post-treatment response to integrated cognitive/motor intervention. During Phase A, the control phase, will be measured at enrollment and at 12 weeks. This 12 weeks measure will serve as the evaluation for both post-Phase A and pre-Phase B. During Phase B, the experimental phase, subjects will be measured at the end of treatment at 12 weeks, and 24 weeks later. In Phase B, the experimental phase, subjects will receive 12 weeks of training.

Experimental treatment will be integrated cognitive and motor training. For both cognitive and motor training, an initial evaluation will determine the initial level of training. Individual daily progress will determine the rate at which both cognitive and motor rehabilitation is progressed. Cognitive rehabilitation and progression will be based on the established Attention Process Training method, with the unique aspect of incorporating an innovative dual cognitive/motor task training paradigm. Motor rehabilitation will be based on established motor skill re-learning methods, incorporating innovative use of robotics and functional electrical stimulation (FES) methods in order to allow productive practice of close-to-normal motor tasks, over a finely incrementalized motor challenge hierarchy that supports the brain plasticity neural functional changes required for re-learning.

Integrated cognitive and motor learning will be extended to the every day environment in order to adhere to the principle of training specificity, and ensure enhancement of function and life role participation.

The primary outcome measure will be the Craig Handicap Rating Assessment Tool (CHART), an established measure of life role of participation for those with TBI. Secondary measures will include cognitive measures of attention, executive function and cognitive planning time; Arm Motor Ability Test (AMAT), an upper limb functional measure; balance; gait coordination; and functional mobility.

Innovation and Significance. The cost of incomplete or inadequate rehabilitation after TBI is devastating to military personnel, veterans, civilians and their families, as well as the military, and society. The proposed treatment is unique in the following ways: 1) accurately based on re-learning principles of brain plasticity and re-learning, for recovery of brain function; 2) innovatively integrates cognitive and motor training; 3) targets a broad array of impairments; 4) utilizes methods with proven efficacy for those having

similar impairments to TBI; and 5) extends the treatment to the real world environment and activities of life role participation. This study has the potential to provide a comprehensive treatment protocol designed to return military personnel, veterans, and civilians to life role participation.

Body
Section II- Brief description of progress

Quarters 1 – 3 : Oct – March 2013

Extensive staff training was completed.
DOD requested that our documents be changed on administrative issues.
We complied with document revisions for administrative issues and submitted revised documents.
We obtained DOD approval for revised documents.
We submitted DOD-revised documents to our local IRB.
We obtained local IRB approval for DOD-revised documents.
We compiled documents for our annual continuing review by our local IRB.
We submitted documents to our local IRB for continuing review.
We obtained IRB approval for our continuing review, late January 2013.

Quarter 4: April – June, 2013

We obtained final DOD approval for documents that had been approved locally.
We screened 3 subjects and one qualified to enroll in the study.
We enrolled Subject QQ in the study.
A complete initial data set was obtained for subject QQ.
Subject QQ completed the control phase of the study (3 months, no treatment).
A complete dataset was obtained for subject QQ at the close of the control phase of the study (3 months).

Section III -Problem Areas

None to report.

No adverse events.

Section IV- Description of work to be performed during the next quarter

Subject QQ will be provided with the intervention protocol, 5hrs/day, 5 days/wk.
Next quarter's work will be performed per the study protocol in the research plan. We will continue to recruit and treat subjects according to the planned protocol.

Section V- Administrative Comments (optional)

None to report.